

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases for which the articles were recommended orally by the defendant, namely, (Formula No. 1 and Formula No. 556) ulcers, (Formula No. 3 and cold salve) arthritis, and (Formula No. 4) diabetes.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 6-11-56.

On 6-20-56, after consideration of the evidence and briefs of counsel, the court handed down its findings of fact, conclusions of law, and verdict of guilty, as reported in 144 F. Supp. 229. On 6-27-56, the court fined the defendant \$2,000, sentenced him to serve 1 year and 1 day in prison, and placed him on probation for a period of 5 years, to begin upon his release from prison.

5144. Tryptacin tablets. (F. D. C. No. 35585. S. Nos. 19-876 L, 39-562 L, 43-165 L, 48-106 L, 64-364 L, 72-361 L.)

INDICTMENT RETURNED: 3-1-55, N. Dist. Ohio, against Rhodes Pharmacal Co., Inc., Cleveland, Ohio, J. Sanford Rose, president, and Jerome H. Rose, vice president and treasurer, of the corporation.

SHIPPED: Between 9-18-52 and 9-29-53, from Ohio to Minnesota, West Virginia, Louisiana, Washington, and California.

LABEL IN PART: (Btl.) "Tryptacin RHODES * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

RESULTS OF INVESTIGATION: The article was represented in its advertising for use in the treatment of stomach ulcers.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the conditions and diseases for which the article was intended to be used and was offered to the public in its advertising, and since the labeling of the article failed also to state the dosage and frequency and duration of administration for the treatment and prevention of such conditions and diseases.

PLEA: Guilty—by corporation; nolo contendere by individuals.

DISPOSITION: 6-29-56. Corporation fined \$5,500; individuals placed on probation for 3 years.

5145. Dextro-amphetamine sulfate tablets. (F. D. C. No. 39204. S. Nos. 18-962 M, 19-483/4 M, 19-486/7 M, 23-854 M, 30-682 M, 31-060 M.)

INFORMATION FILED: 12-11-56, S. Dist. Ohio, against Ace Tablet Co., a partnership, Steubenville, Ohio, and Rinaldo D. Tarquinio, partner.

SHIPPED: Between 10-12-55 and 3-17-56, from Ohio to Arizona, Tennessee, and Kentucky.

LABEL IN PART: (Btl.) "Tablets Dextro Amphetamine Sulfate 5 Mg. Caution: Federal law prohibits dispensing without a prescription."

RESULTS OF INVESTIGATION: The tablets were shipped to persons who were not authorized to receive them.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.

DISPOSITION: 12-19-56. Defendant fined \$800 and placed on probation for 3 years.

5146. *Gassup*. (F. D. C. No. 39297. S. No. 48-342 M.)

QUANTITY: 643 2-oz. btls. in 4 cases at Newark, N. J.

SHIPPED: 6-20-55, from Brooklyn, N. Y., by Manhattan Drug Co.

LABEL IN PART: (Btl.) "Gassup * * * Active Ingredients Magnesium Trisilicate * * * Gastom Chemical Company, Newark, New Jersey."

ACCOMPANYING LABELING: Leaflet designated "Gassup * * * Indicated in the treatment of Acidity."

LIBELED: On or about 7-18-56, Dist. N. J.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an effective treatment for indigestion and autointoxication; that it would relieve the pain of hemorrhoids; that it would prevent rheumatism; that it would reduce the accumulation of fat in the body, relieve headaches and dizziness, and prevent colds; that it would restore normal metabolism in the body; and that it was safe and suitable for continuous use; and 502 (f) (2)—the labeling of the article failed to bear a warning that frequent or continued use might lead to a dependence on laxatives.

DISPOSITION: 8-22-56. Default—destruction.

5147. *Monazite sand*. (Inj. No. 292.)

COMPLAINT FOR INFORMATION FILED: 11-1-55, W. Dist. Wash., against Raco, Inc., Seattle, Wash., and George Kosmos, president of the corporation.

LABEL IN PART: (Pad) "Cosmos Radioactive Pad * * * Place Pad Under Pillow or Mattress."

ACCOMPANYING LABELING: Placards entitled "The Radioactive Material in the Cosmos Radioactive Pad," "Arthritis? Bursitis?" and "Idaho Bursitis? Rheumatism? * * * Get the Cosmos Pad"; "blowup" photographs of an article entitled "Now—An Atomic Drugstore" taken from the January 21, 1955, issue of *Colliers Magazine*; copies of the January 21, 1955, issue of *Colliers Magazine*; leather-bound ring binders containing testimonial letters; and circulars entitled "Arthritis Bursitis Rheumatism."

CHARGE: The complaint alleged that the defendants caused an article known as *monazite sand* to be brought in bulk to Seattle, Wash., from places outside the State of Washington and to be packaged into pads labeled as described above; that, while the defendants held the sand and the pads for sale at Seattle, Wash., they caused such articles to be accompanied by the above-mentioned labeling and to be introduced into interstate commerce accompanied by such labeling.

The complaint alleged also that the articles, when introduced into interstate commerce, when received in interstate commerce, and while held for sale after shipment in interstate commerce, were misbranded as follows:

502 (a)—the labeling contained false and misleading representations that the articles provided an adequate and effective treatment for arthritis, bursitis, rheumatism, neuritis, and sinus trouble, and soreness of hands, wrists, forearms, and back; and